

K022828
APR - 2 2004

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of OSTEORESET® DBM Pellets.

Submitted By: **Wright Medical Technology, Inc.**

Date: February 16, 2004

Contact Person: **Roger D. Brown**
Sr. Director, Clinical and Regulatory Affairs

Proprietary Name: OSTEORESET® DBM Pellets

Common Name: Bone Void Filler

Classification Name and Reference: Filler, Calcium Sulfate Preformed Pellets – Class II,
888.3045

Device Product Code and Panel Code: Orthopedics/MQV

DEVICE INFORMATION

A. INTENDED USE

OSTEORESET® DBM Pellets are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. OSTEORESET® DBM Pellets are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

B. DEVICE DESCRIPTION

OSTEORESET® DBM Pellets are made of surgical grade calcium sulfate incorporating Human Demineralized Bone Matrix (DBM) and stearic acid as a tableting aid. OSTEORESET® DBM Pellets are provided as preformed 3.0 mm or 4.8 mm pellets. The biodegradable, radiopaque pellets are used to fill bone voids and are resorbed in approximately 30-60 days when used according to labeling. This product is supplied sterile for single patient use.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, materials, and mode of action of OSTEORESET® DBM Pellets are substantially equivalent to the predicate device. The safety and effectiveness of OSTEORESET® DBM Pellets is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

DBM Osteoinductivity Potential Testing

The DBM incorporated into OSTEORESET® DBM Pellets is assayed *in vitro* for its osteoinductive potential. The bioassay measures the proliferation of Saos human osteosarcoma cells in the presence of human DBM compared to positive and negative controls (osteoinducitvity index).¹ Results from the bioassay were correlated with results from implantation of DBM into athymic rat muscle², which demonstrated a correlation coefficient of 0.850 ($p<0.0005$)¹ and accurately predicted the *in vivo* osteoinductivity of 99 of 101 donor lots. Additionally, clinical results using DBM with >0.20 and ≤0.20 demonstrated a significant difference in healing as evaluated by radiography, 92% and 33% healing, respectively.³

- 1 Adkisson HD, Strauss-Schoenberger J, Gillis M, Wilkins R, Jackson M, and Hruska KA. Rapid Quantitative Bioassay of Osteoinduction, *J Ortho Res*, 2000, 18:503-511.
- 2 Lindholm TS, Urist MR. A quantitative analysis of new bone formation by induction in composite grafts of bone marrow and bone matrix, *Clin Orthop* 1980 Jul-Aug;(150):288-300.
- 3 Wilkins RM, Clinical Effectiveness of Demineralized Bone Matrix Assayed in Human Cell Culture, *Advances in Tissue Banking*. 1999 3:113-124

The osteoinductivity of the OSTEORESET® DBM Pellets has not been established and it is unknown how osteoinductivity of the DBM component, measured via the *in vitro* bioassay, will correlate with human clinical performance of Osteoset DBM Pellets.

Viral Inactivation Potential

The method for processing the DBM contained in OSTEORESET® DBM Pellets was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes, and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing method for a wide spectrum of potential human viruses.

Product Performance Testing

Performance of OSTEORESET® DBM Pellets was compared to the predicate device in a canine model by radiographic, mechanical, histological and quantification of new bone formation. There was no difference in radiographic, mechanical, histological and quantification of new bone formation at the end of the study.

**DEPARTMENT OF HEALTH & HUMAN SERVICES****Public Health Service**

**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850**

APR - 2 2004

Roger D. Brown
Director, Regulatory Affairs
Wright Medical Technology
5677 Airline Road
Arlington, Tennessee 38002

Re: K022828

Trade Name: OSTEOSSET DBM

Regulation Number: 21 CFR 888.3045

Regulation Name: Resorbable calcium salt bone void filler device

Regulatory Class: Class II

Product Code: MQV, MBP

Dated: January 6, 2004

Received: January 7, 2004

Dear Mr. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

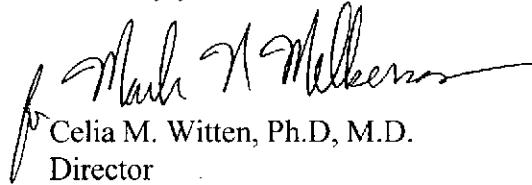
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and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D, M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS STATEMENT

510(K) Number (if known): K022828

Device Name: OSTEOSET® DBM Pellets

Indications for Use:

OSTEOSET® DBM Pellets are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. OSTEOSET® DBM Pellets are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

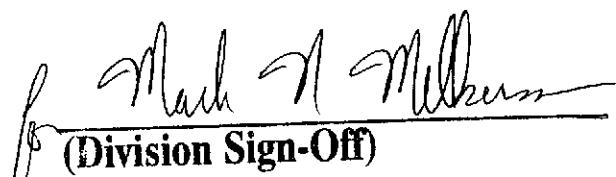
Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Mark H. Millman
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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